



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Ahmed *et al.*

Appl. No.: 10/677,243

Filed: October 3, 2003

For: **Bisphosphonate Composition and
Process for the Preparation Thereof**

Confirmation No.: 9114

Art Unit: 1614

Examiner: To be assigned

Atty. Docket: 2710.0480001/JMC/RLP

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying PTO/SB/08a and PTO/SB/08b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Applicants have listed publication dates on the attached PTO/SB/08a and PTO/SB/08b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent

application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicants have checked the appropriate boxes below.

- ☐ 1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- ☒ 2. Filing under 37 C.F.R. § 1.97(b). This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.
- ☐ 3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.
 - ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first

cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

☐ c. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$_____ in payment of the fee under 37 C.F.R. § 1.17(p).

☐ 4. Filing under 37 C.F.R. § 1.97(d) This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Enclosed find our PTO-2038 Credit Card Payment Form in the amount of \$_____ in payment of the fee under 37 C.F.R. § 1.17(p); in addition:

☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 5. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☒ 7. Copies of documents AA1-AZ1, BA1, BB1 and AA2-AW2, are not provided herewith, since this application was filed after June 30, 2003 and each reference is a U.S. Patent document, in accordance with the PTO Notice 1276 Off. Gaz. Pat. Off. 55, published August 5, 2003.
- ☐ 8. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a and PTO/SB/08b, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

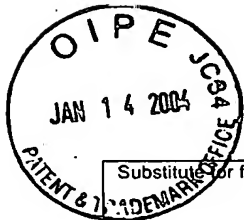


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Date: January 14, 2004

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

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of

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Complete If Known

Application Number	10/677,243
Filing Date	October 3, 2003
First Named Inventor	Ahmed, et al.
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2710.0480001/JMC/RLP

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (If Known)			
	AA1	US-3,962,432	06/08/1976	Schmidt-Dunker	
	AB1	US-4,054,598	10/18/1977	Blum et al.	
	AC1	US-4,086,334	04/25/1978	Schmidt-Dunker et al.	
	AD1	US-4,134,969	01/16/1979	Schmidt-Dunker	
	AE1	US-4,267,108	05/12/1981	Blum et al.	
	AF1	US-4,304,734	12/08/1981	Jary et al.	
	AG1	US-4,327,039	04/27/1982	Blum et al.	
	AH1	US-4,407,761	10/04/1983	Blum et al.	
	AI1	US-4,418,068	11/29/1983	Jones	
	AJ1	US-4,621,077	11/04/1986	Rosini et al.	
	AK1	US-4,624,947	11/25/1986	Blum et al.	
	AL1	US-4,705,651	11/10/1987	Staibano	
	AM1	US-4,711,880	12/08/1987	Stahl et al.	
	AN1	US-4,746,654	05/24/1988	Breliere et al.	
	AO1	US-4,761,406	08/02/1988	Flora et al.	
	AP1	US-4,812,311	03/14/1989	Uchtman	
	AQ1	US-4,922,007	05/01/1990	Kieczkowski et al.	
	AR1	US-4,927,814	05/22/1990	Gall et al.	
	AS1	US-4,927,855	05/22/1990	Lafon	
	AT1	US-4,971,958	11/20/1990	Bosies et al.	
	AU1	US-4,980,171	12/25/1990	Fels et al.	
	AV1	US-4,980,272	12/25/1990	Kuse et al.	
	AW1	US-5,019,651	05/28/1991	Kieczkowski	
	AX1	US-5,096,717	03/17/1992	Wirth et al.	
	AY1	US-5,159,108	10/27/1992	Kieczkowski	
	AZ1	US-5,227,506	07/13/1993	Saari et al.	
	BA1	US-5,358,941	10/25/1994	Bechard et al.	
	BB1	US-5,393,763	02/28/1995	Black et al.	

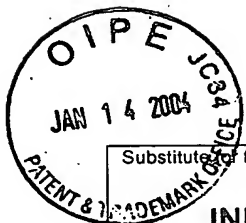
Examiner Signature

Date
Considered

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete If Known

Application Number	10/677,243
Filing Date	October 3, 2003
First Named Inventor	Ahmed, et al.
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2710.0480001/JMC/RLP

Sheet	2	of	3
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Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (If Known)			
	AA2	US-5,431,920	07/11/1995	Bechard	
	AB2	US-5,457,117	10/10/1995	Black et al.	
	AC2	US-5,449,819	09/12/1995	Venkataramani et al.	
	AD2	US-5,488,041	01/30/1996	Barbier et al.	
	AE2	US-5,510,517	04/23/1996	Dauer et al.	
	AF2	US-5,648,491	07/15/1997	Dauer et al.	
	AG2	US-5,616,571	04/01/1997	Daifotis et al.	
	AH2	US-5,681,590	10/28/1997	Bechard et al.	
	AI2	US-5,804,570	09/08/1998	Santora, II et al.	
	AJ2	US-5,849,726	12/15/1998	Brenner et al.	
	AK2	US-5,882,656	03/16/1999	Bechard et al.	
	AL2	US-5,908,959	06/01/1999	Kubela et al.	
	AM2	US-5,944,329	08/31/1999	Salzer et al.	
	AN2	US-6,008,207	12/28/1999	Brenner et al.	
	AO2	US-6,015,801	01/18/2000	Daifotis et al.	
	AP2	US-6,090,410	07/18/2000	Bechard et al.	
	AQ2	US-6,194,004	02/27/2001	Bechard et al.	
	AR2	US-6,225,294	05/01/2001	Daifotis et al.	
	AS2	US-6,399,592	06/04/2002	Whiteford	
	AT2	US-6,544,967	04/08/2003	Daifotis et al.	
	AU2	US-2001/005166	06/28/2001	Coulombier	
	AV2	US-2001/001306	05/17/2001	Daifotis et al.	
	AW2	US-RE37,516	01/15/2002	Grebow et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ⁴ Kind Code ⁵ (in known)				
	AX2	EP-0600834	06/08/1994	Goodship et al.		
	AY2	WO-93/11786	06/24/1993	Geddes et al.		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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Sheet	3	of	3
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		Country Code* Kind Code ⁵ (in known)				
	AA3	WO-95/28145	10/26/1995	Shinoda, et al.		
	AB3	WO-95/30421	11/16/1995	Goodship et al.		
	AC3	CA-2,018,477	12/09/1990	Kieczkowski, et al.		

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M PEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Transaction is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Application Number

10/677,243

Filing Date

October 3, 2003

First Named Inventor

Ahmed, et al.

Art Unit

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Examiner Name

To be assigned

Sheet

1

of

1

Attorney Docket Number

2710.0480001/JMC/RLP

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	AA4	"Update: Bisphosphonate," <u>Lunar News</u> (Journal of the Lunar Corporation), July 1996, p. 23-24.	
	AB4	"Update: Bisphosphonate," <u>Lunar News</u> (Journal of the Lunar Corporation), April 1996, p. 31.	

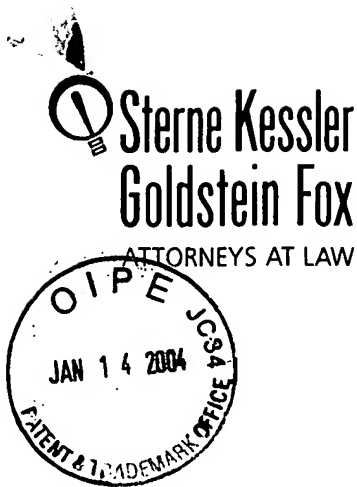
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January 14, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1614

Re: U.S. Utility Patent Application
Application No. 10/677,243; Filed: October 3, 2003
For: **Bisphosphonate Composition and Process for the Preparation Thereof**
Inventors: Ahmed *et al.*
Our Ref: 2710.0480001/JMC/RLP

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Three pages of Form PTO/SB/08a citing 56 documents;
3. One page of Form PTO/SB/08b citing two documents;
4. Copies of the documents as listed on Form PTO/SB/08a and Form PTO/SB/08b (AX2, AY2, AA3-AC3, AA4 and AB4) and;
5. One (1) return postcard;

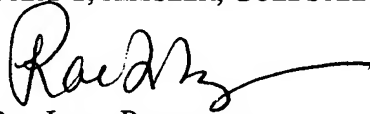
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
January 14, 2004
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read 'Rae Lynn', with a long horizontal flourish extending to the right.

Rae Lynn Prengaman
Attorney for Applicants
Registration No. 53,482

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218591_1.DOC